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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,180	07/15/2003	Arnold Keller	246472005500	4977

7590 03/02/2005
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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/619,180

Applicant(s)

KELLER, ARNOLD

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for forceps, does not reasonably provide enablement for the term "pliers." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether applicant is positively reciting the multi-part endoprosthesis as part of the insertion instrument or if the prosthesis is simply a statement of intended use. As claim 1 is written, it can be interpreted that the endoprosthesis is only part of the intended use recitation in the preamble. As claim 13 is written, it can be interpreted that the limitation "two closure plates and a sliding core arranged between the closure plates" is part of the insertion instrument instead of a separate prosthesis. Examiner suggests specifying in claim 13 that the limitations in line 3 are directed toward the structure of the prosthesis.

Claims 1 and 13 first recite "projections pointing in a clamping direction OR recesses for holding the intervertebral endoprosthesis." Only the projections are required to be directed in a "clamping direction." The claims go on to state "tensioning direction different from the clamping direction." This is

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indefinite, because "the clamping direction" would not apply when recesses were used instead of projections.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,431,658 to Moskovich.

Moskovich discloses an intervertebral prosthesis insertion tool that meets the limitations of claim 1. The device includes two gripping members (11,12) connected by a hinge (13), as illustrated in Figure 4. The gripping members have grooved surfaces (shown in Figure 3) for supporting the prosthesis (column 3, lines 1-7). These grooves are considered to meet the limitation "or recesses for holding the intervertebral endoprosthesis." The proximal ends of the gripping members are capable of functioning as handgrips. Moskovich further explains here that the surface could have raised ridges. Figure 6 shows the hinged gripping members (1,2) connected to an actuating device (21), which includes a threaded rod (25) with a handle (22) that could also function as a force receiving part or "strike head." A block (26) at the end of the rod is positioned between the gripping members (1,2) and is moved longitudinally by the actuating device (21) to bear on a prosthesis (5) (column 3, lines 36-38). The insertion instrument could be described as "forceps" or "pliers." Nut (23) includes a counter thread for receiving the rod (25). It is interpreted that the endoprosthesis is only a part of the recitation of intended use in the preamble of claim 1. The Moskovich device is capable of being used to insert a prosthesis with two plates and a sliding core, so it meets the limitations of this claim.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,431,658 to Moskovich in view of US Patent No. 6,368,350 to Erickson et al.

As explained above, Moskovich discloses an intervertebral prosthesis insertion tool that meets most of the limitations of claim 13. Moskovich fails to show that the endoprosthesis inserted by the device is comprised of two closure plates and a sliding core. Moskovich only illustrates a generic spinal implant (5). Erickson discloses an endoprosthesis with two plates (20,21) surrounding a sliding core (22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to insert the Erickson prosthesis with the Moskovich device in place of the generic implant (5), as this is simply one type of spinal implant that is capable of being inserted with the Moskovich device.

5. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moskovich in view of US Patent No. 3,960,147 to Murray.

Moskovich includes all the limitations of claims 4 and 5, except for positioning the threaded nut (23) within the hinge. Murray discloses another forceps type instrument that includes two hinged gripping members (18,19) and a threaded actuating rod (26). Murray teaches by illustration that a counter threaded part (25) that receives a threaded actuating rod may be positioned in the hinge (24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to arrange the hinge and

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threaded nut of Moskovich so the threaded nut is positioned within the hinge, as Murray teaches that this another way to form a forceps with a threaded actuating rod.

6. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moskovich in view of Erickson, as applied to claims 13-15 above, and further in view of Murray.

Moskovich nad Erickson include all the limitations of claims 16 and 17, except for positioning the threaded nut (23) within the hinge. Murray discloses another forceps type instrument that includes two hinged gripping members (18,19) and a threaded actuating rod (26). Murray teaches by illustration that a counter threaded part (25) that receives a threaded actuating rod may positioned in the hinge (24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to arrange the hinge and threaded nut of the modified Moskovich insertion system so the threaded nut is positioned within the hinge, as Murray teaches that this another way to form a forceps with a threaded actuating rod.

7. Claims 7,9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moskovich in view of US Patent No. 5,720,751 to Jackson.

Moskovich includes all the limitations of claims 7,9 and 11, except for a locking device with a guide for the actuating rod. Jackson discloses another type of implant grasping device in that includes hinged members and a threaded actuation rod (5) attached to an implant abutment part (20). Figure 24 illustrates an embodiment of the invention that includes a toothed locking device (290,289) for securing the handgrip parts (286,287) pressed together (column 15, lines 34-42). One toothed member (289) of the locking device includes a receptacle (292) with a threaded bore for guiding the actuating rod (5) (column 15, line 46). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a locking device with a threaded bore on the gripping plates (1,2) of Moskovich, as Jackson teaches that this structure aids the surgeon in securing the hinged members in a closed position.

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8. Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moskovich in view of US Patent Application Pub. 2002/0072752; Zucherman et al.

Moskovich includes all the limitations of claims 8 and 10, except for the projections being arranged on removable jaw inserts. Zucherman discloses another type of instrument that also performs the function of distracting vertebrae. Zucherman teaches that gripping members with projections can be formed as detachable inserts [0048]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the gripping members of Moskovich as detachable inserts, as Zucherman teaches that this is another way to form a vertebrae distracting instrument.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moskovich in view of Zucherman, as applied to claim 8 above, and further in view of Jackson.

Moskovich includes all the limitations of claim 8, except for a locking device with a guide for the actuating rod. Jackson discloses an implant insertion device in that includes hinged members and a threaded actuation rod (5) that abuts an implant. Figure 24 illustrates an embodiment of the invention that includes a toothed locking device (290,289) for securing the handgrip parts (286,287) pressed together (column 15, lines 34-42). One toothed member (289) of the locking device includes a receptacle (292) with a threaded bore for guiding the actuating rod (5) (column 15, line 46). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a locking device with a threaded bore on the gripping plates (1,2) of Moskovich, as Jackson teaches that this structure aids the surgeon in securing the hinged members in a closed position.

Response to Arguments

10. Applicant's arguments filed 12/2/04 have been fully considered but they are not persuasive.

Applicant states that examiner has not differentiated the claimed insertion instrument from the

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endoprosthesis being inserted in the Moskovich reference. In response to this argument, examiner asserts that applicant has not differentiated the claimed insertion instrument from the endoprosthesis being inserted in the independent claims. As claim 1 is currently written, it can be interpreted that the endoprosthesis is only part of the intended use recitation in the preamble. As claim 13 is currently written, it can be interpreted that the limitation "two closure plates and a sliding core arranged between the closure plates" is part of the insertion instrument. Nonetheless, examiner has included a prosthesis in the rejection of claim 13 that meets this limitation.

Applicant argues that the grooves of the Moskovich device extend parallel to the "tensioning direction" of the block. As the claim limitations are written, "recesses" are not required to extend in the "clamping direction" that is different than the "tensioning direction."

11. In response to applicant's argument that Moskovich does not include a "force-receiving part", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. There are no structural limitations in the claims for the "force-receiving part" that would distinguish the claimed structure from the structure of Moskovich.

12. In response to applicant's argument that Moskovich works in a way that is entirely different from the claimed insertion instrument, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As explained in more detail above, the modified Moskovich device includes all the structural limitations of the claimed invention, so it meets the claim requirements.

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Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,759,766 to Buettner-Janz et al. discloses another spinal prosthesis that is formed by two plates and a core.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

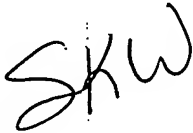
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhthuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
2/23/05



JULIAN W. WOO
PRIMARY EXAMINER